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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,403	04/08/2004	Taka-Aki Sato	0575/65823-A	8435

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EXAMINER	
WESSENDORF, TERESA D	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/820,403	SATO, TAKA-AKI	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 16-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 16-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-9 and 16 in the reply filed on 6/18/05 is acknowledged. Applicants requests that the Examiner reconsider and withdraw the restriction requirement. Under M.P.E.P. 5803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. The inventions of Group (claims 1-9) and Group II (claims 10-12) and Group III (claims and 20) are not independent. Under M.P.E.P. 5802.01, "independent" means there is no disclosed relationship between the subjects disclosed. Each of the claims of the Groups is dependent from either claim 1 or 16. Applicant maintains that it would not be a serious burden on the Examiner if restriction is not required in view of the claim dependencies a search of the prior art for Group I would necessarily identify art for Groups II and III. Applicant therefore maintains that the search and examination of the claims of Group II and Group III in addition to the claims of Group I would not be a serious burden on the Examiner. Since there is no burden on the Examiner to examine Groups I, II and III of the subject application, the

Examiner should examine the inventions of Groups I, II and III on the merits together.

Upon reconsideration of the restriction requirement, applicant's request and traversal, the restriction has been withdrawn. All of the claims would be examined.

Status of Claims

Claims 1-13 and 16-20 are pending and under examination.

Specification

The disclosure is objected to because of the following informalities:

1. The status of applications S.N. 08/681,219 or 09/230,111 recited at page 17, lines 7-10 have not been provided.

2. There is no Seq. ID. No. for sequence GLGF recited at page 2, line 27 of the instant specification. Applicants are requested to check for other Sequences in the specification that do not have ID. Nos. and to make certain the sequences are in the Sequence Listing and CRF. Appropriate correction is required.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 10-13 and 16-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To satisfy a written description requirement for a claimed genus a sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406. A representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within

the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure indicates that the applicant has invented species sufficient to constitute the gen[us]. Noelle v. Lederman, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004).

The specification provides a written description of proteins in array (beads). It does not provide a description of the claimed generic method wherein the array comprises the other elements such as oligonucleotide, DNA, mRNA and sugar. The specification provides only a list of these other elements. A laundry list disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species. In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967). It is not readily apparent from the disclosure whether these other elements form a part of the protein i.e., conjugated or are separate and distinct components of the array. The specification and claim recite for protein-protein interaction between the components in the array(first protein) and the interacting(second) protein. It does not describe the interaction of a protein-nucleic acid or protein-sugar. The examples do not provide correlation of the

single species to the huge scope of the other elements. Neither does it describe the type or kind, location, length of each of the elements that can be contained in an array or the protein that it interacts with. An applicant of a biotechnological invention cannot necessarily claim a genus after only describing a single species because there may be unpredictability in the results obtained from species other than those specifically described. The disclosure does not describe how each of these components in the array are separated such that the elements do not interact with each other and would only interact with the added protein. Applicant, at the time of filing, is deemed to have not invented species sufficient to constitute the genus by virtue of having disclosed a single species when … the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed. In re Curtis, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004). To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the genus of the invention. As of the filing date, applicant does not seem to have possession of the claimed method with an array containing the other generic elements.

The specification further fails to describe a method wherein the array contains polypeptide rather than protein. There is no description in the specification as to the distinguishing characteristics of a protein from a polypeptide or what constitutes a polypeptide, within the claimed method.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 10-13 and 16-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claims 10-13 and 17-20 are inconsistent with claims 1 and 16, respectively. It is not clear how a protein-protein interaction, as recited in claim 1 and 16, occur between the structurally different elements of the array e.g., sugar.

2. Claim 3 is indefinite and broadens the base claim 1 with the recitation that the "array is used to screen one or more drug targets". This claim relates to a method of use rather than a method of preparing. The base claim recites only a method of

preparing and not a screening method, which would include other steps such that screening would be achieved.

3. Claim 16 appears to be a duplicate of claim 1, especially since the specification does not provide a differentiating characteristic between a polypeptide and a protein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doyle (Cell) in view of any one of applicant's disclosure of known prior art or Schneider-Mergener (Comparative and Functional Genomics) or Harris et al (Jrnl. of Cell Science).

Doyle discloses, page 1067 a modular PDZ domain that binds to the peptide motif T/S-X-Val at the C-terminus of protein K Channels and NMDA receptor ion channels. Doyle further discloses at page 1072 that Val can be varied with Ile. Doyle does not

disclose a method of preparing an array for the PDZ domain with its receptor. However, applicant discloses at page 3, lines 23-34 that a "recent trend in biology, biotechnology and medicine is the use of arrays of immobilized biological compounds in studies of immunoassays and enzymatic reactions (see Mendoza….) For example, mass sensing, multianalyte microarray immunoassays have been performed (Rowe et al…) The use of arrays allows for large scale and high-throughput studies of multiple samples in parallel. Integration of microarray technology into the experimental methodology also may increase efficiency in many instances, such as through reducing the volume of samples and reagents required.." Harris et al disclose an array of target proteins to which PDZ containing proteins bind to. See the abstract. Schneider discloses that an array is a versatile toolbox for a variety of application in proteomics. See the abstract. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare or to format the PDZ domains of Doyle into an array since forming a compound into an array will provide a high-throughput screening for a desired receptor or ligand, as taught by applicant's disclosure and Schneider. This is evident from the teachings of Harris, which discloses an array of target receptors for the PDZ domain. The numerous advantages cited by

applicant's disclosure and Schneider provides the motivation to one having ordinary skill in the art to make an array for the different PDZ domains.

Claim 16 is obvious over the teachings of Doyle as to the proteins or polypeptides of PDZ domain at page 1067, col. 2.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-9 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-8 of prior U.S. Patent No. 6,743,630. This is a double patenting rejection.
[This rejection is based on the interpretation that the first protein deposited on the array comprises different proteins having PDZ domain.]

The instant claimed method is coextensive in scope with the '630 Patent. The instant application recites a first protein or polypeptide comprising a PDZ domain. It is considered that the

first protein of the instant method is the same as the '630 first protein**s** since an array cannot contain only one protein. Rather, different proteins each comprising a PDZ domain. Thus, this claim which recites a first protein in the singular is the same as the method of the '630 Patent which recites the first protein**s** in the plural.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,743,630. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed method of producing an array containing a single protein is

encompassed by the 630 Patent which includes said single protein in the plurality of proteins.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Yue et al discloses the different types of PDZ domain proteins.

Claims 10-13 and 17-20 are free of prior art.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is(571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner s supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
April 15, 2005